: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS-OASH-2022-0014]

Draft Guidance on Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document titled, "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions."

DATES: Submit written comments by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may send comments, identified by docket number HHS-OASH-2022-0014, by any of the following methods:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments.
- E-mail: OHRP@hhs.gov
- Fax: 240-453-8420
- Mail/Hand Delivery/Courier: Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Instructions: All submissions received must include the docket number. All comments received, including attachments and any personal information, will be posted without change to https://www.regulations.gov.

Submit written requests for a single copy of the guidance document titled, "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions" to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 240-453-8420. See the **SUPPLEMENTARY INFORMATION** section for information on access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6700; email natalie.klein@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP is announcing the availability of a draft guidance document for public comment titled "Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions." The draft guidance document applies to research activities involving human subjects that are conducted or supported by HHS. It is intended primarily to help entities implement the requirement for limited review of research by an IRB to meet the conditions of four exemptions found at 45 CFR 46.104(d) of the 2018 Requirements (the Common Rule). The draft guidance discusses the concept of limited IRB review, which appears in these exemptions, and provides information about how limited review may be conducted. When finalized, this will provide OHRP's first formal guidance on this topic. This draft guidance was developed after taking into consideration input received from HHS and other Common Rule departments and agencies.

II. Equity and Justice Considerations

OHRP is particularly interested in public comments on any impact this guidance may have on considerations for equity and justice in human research protections.

III. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html.

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Office for Human Research Protections.

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